

Attorney Docket No.: DEX-0172
Inventors: Salceda et al.
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REMARKS

Claims 14, 21-28 and 35-49 are pending in the instant application. Claims 14, 21-28 and 35-49 have been rejected. Reconsideration is respectfully requested in light of the following remarks.

Claims 14, 21-28 and 35-37 remain rejected and new claims 38-49 have been rejected under 35 U.S.C. 101 because the Examiner suggests that the claimed invention is not supported by either a substantial asserted utility or a well established utility. These claims have also been rejected under 35 U.S.C. 112, first paragraph, because the Examiner suggests that without support of a substantial asserted utility or a well-established utility, one skilled in the art would not know how to use the claimed invention. These claims have also been rejected under 35 U.S.C. 112, first paragraph for lack of written description.

Arguments presented by Applicants in the last response inclusive of the Declaration by Dr. Susana Salceda were suggested by the Examiner not to be persuasive. Specifically, the Examiner states that while "there were routinely used methods at the time of filing that would have enabled one of skill in the art to identify *potential* open reading frames from an mRNA sequence", "one of skill in the art would have no reason to assume that the open reading frame would "encode many amino acids" and that the

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largest open reading frame identified by the computer would be *the* protein encoded by SEQ ID NO:1." The Examiner suggests that from the information provided in the specification, there is no reason to believe that the protein of SEQ ID NO:1 would not be encoded by other smaller open reading frames diagramed in the Declaration's figures.

Applicants respectfully traverse these rejections.

In addition to the methods acknowledged by the Examiner to be available at the time of filing that would have enabled one of skill in the art to identify *potential* open reading frames from an mRNA sequence, also known as of the filing date of the instant application was that the sequence flanking functional initiator codons in eukaryotic mRNA sequence is a nonrandom sequence, referred to as the Kozak consensus sequence (see Kozak, M. Nucleic Acids Research 1981 9(20):52335262; Kozak, M. Nucleic Acids Research 1984 12(2):857-872; and Kozak, M. Nucleic Acids Research 1987 15(20):8125-8148; copies of these references are submitted in the Supplemental Information Disclosure Statement filed herewith).

Because the sequence and expression data of SEQ ID NO:1 was based on an mRNA molecule, one of ordinary skill would know the correct orientation to be 5'-3'. Given the orientation, one of ordinary skill could readily scan the

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entirety of SEQ ID No. 1 examining any of the three possible frames for a start codon identified by the Kozak consensus sequence. The first ATG start codon in frame 2 and the flanking sequence, CCAGCCATGG, meets the requirements for an initiator codon as identified by the Kozak eukaryotic sequence. This ATG is the same ATG identified by Dr. Salceda in her declaration as the start of the open reading frame for the protein encoded by SEQ ID No. 1.

Also known as of the filing date of the instant application was that the 5'-proximal ATG serves as the initiator codon for the majority of mRNAs (see Kozak, M. Nucleic Acids Research 1984 12(2):857-872; Singer, M. and Berg, P. Genes & Genomes 1991 University Science Books (Mill Valley, CA), pages 180-182; and Watson et al. Molecular Biology of the Gene 1987 The Benjamin/Cummings Publishing Company, Inc. (Menlo Park, CA), pages 568-569; copies of these references are submitted in the Supplemental Information Disclosure Statement filed herewith).

As stated above, since the sequence and expression data of SEQ ID NO:1 was based on an mRNA molecule, one of ordinary skill would know the correct orientation to be 5'-3'. In this orientation, frame 2 contains the 5'-proximal ATG start codon, which is the start of the open reading

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frame for the protein encoded by SEQ ID No. 1. This ATG is the same ATG identified by Dr. Salceda in her declaration as the start of the open reading frame for the protein encoded by SEQ ID No. 1.

Thus, contrary to the Examiner's suggestion, the information provided in SEQ ID NO:1 itself, coupled with teachings in the specification in Examples 1 and 2 regarding the sequence and expression data of SEQ ID NO:1 being based on an mRNA molecule and having a set 5' to 3' orientation, the methods available as of the filing date of the application which are outlined in Dr. Salceda's Declaration and acknowledged by the Examiner to be enabling for identifying potential open reading frames and what was known in the art regarding translation initiation of eukaryotic mRNA sequences, demonstrates Applicants' possession of **the protein** encoded by SEQ ID NO:1 and provides the required enablement for one of skill in the art at the time of filing the instant application to make and use **the protein** encoded by SEQ ID NO:1 and antibodies thereto.

MPEP 2163, MPEP 2164.01 and the case law are clear; information which is well known in the art need not be described in detail in the specification. See, e.g. Hybritech, Inc. v. Monoclonal Antibodies, Inc. 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).

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Accordingly, detailed teachings in the specification of the methods available for identifying the open reading frame, the initiator codon based on the Kozak consensus sequence and the 5' proximal ATG are not required to meet the written description and enablement requirements of 35 U.S.C. 112, first paragraph.

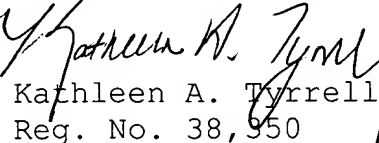
Thus, the instant specification clearly meets the statutory requirements of 35 U.S.C. 101 and 35 U.S.C. 112.

Withdrawal of all rejections is therefore respectfully requested.

Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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Date: **April 26, 2006**

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